Cobe Centrysystem 3 Service Manual

Hydraulics Description of Centrysystem 3 Flow-path with BiCart Priming Enhancement:

I) "Dialysate Prep" Module

1. Water inlet supply hose with filter washers: It connects the machine to the treated water supply, is composed of two 158-micron filter washers where one is an in faucet connector while the other is for downstream use (protection purposes), traps small particles that might affect the operation of the hydraulic components, and should be inspected and cleaned after every 100 hours of service.

2. Accessory water filter (optional): Instead of using a second 158-micron filter, an accessory water filter can be installed.

II) Dialysate Prep "Fluid" Section

1. Inlet water pressure regulator (PR-1): It is an adjustable forward-pressure regulator which is used to reduce the pressure of incoming water (15 to 125 PSI) to about 600 mmHg at the inlet solenoid valve V1.

2. Inlet water valve (V1) and Brown Restrictor: V1 is a normally closed 24 V solenoid valve which opens when the main power is switched on. It allows the supply of water to flow into the machine when opened; on the other hand, it prevents the flow whenever the power is switched off or when the machine is in ACDR mode (preacetate, acetyl acetate, or chloride), as in disinfection dwell mode or chemical recirculation mode. The normal operation of the valve V1 is on and off pulsations where a Hall-effect level sensor LS1, located in the heater and deaeration chamber, monitors the H_2O level in the machine as V1 operates. The dialysate prep control microprocessor uses LS1's signal to control V1. The system generates "HEATER CONTROL DISABELED" alarm if the duty cycle of V1 is too high or too low. Note that some system alarms may automatically override normal operation and cause valve V1 to close. As for the brown flow restrictor, it is located in the tubing segment between PR1 and V1. It dampens the pressure surges when V1 opens or closes and helps in moderating the flow of water into the heater and deaeration chamber to maintain the output signal of LS1 linear and stable.

3. Heat Exchanger: It uses warm dialysate effluent to preheat incoming water, has a thermally conductive stainless steel plate that separates fresh H_2O from the effluent side of the flow path, and uses a counter-current flow for maximum heat transfer. It holds about 60 mL of fluid per side and operates at 70% efficiency which allows the use of a smaller water heater and the decrease of power consumption.

4. Pre-heater thermistor (T0): It is a control thermistor that is used to monitor the temperature of water flowing out of the heat exchanger and into the heater and deaeration chamber. Along with T1, it controls the heater's duty cycle and minimizes the system warm-up time. A "DP THERMISTOR ERROR" alarm is generated if T0 indicates a temperature reading below 6ºC.

5. Inlet water flow switch (FS3): The flow in a Cobe Centrysystem 3 is regularly maintained between 300 and 700 mL/min. FS3 is a normally-open flow switch which closes when the flow rate exceeds 200 mL/min. It detects low flows (or absence of flow) when the flow rate decreases beyond 200 mL/min. The voltage of FS3 is sensed by the dialysate prep control and monitor microprocessor. The voltage reads zero when the switch is closed and +4 V DC otherwise. FS3 is controlled by V1; thus, when V1 closes, FS3 must indicate no flow for 10 seconds. If the duration for which no flow is indicated at FS3 exceeds 10 seconds, the heater is turned off, and the alarms "NO WATER" and "HEATER CONTROL DISABELED" are indicated.

6. Heater and deaeration chamber: The chamber is consisted of a 700 mL container with:

    a. 800 W heater (H1): The heater controls the temperature of the dialysate solution (the voltage required to operate the heater is 115 V AC or 230 V AC since it is composed of identical partitions 400 W heating elements).
    b. Small polypropylene pellets: It aids in the deaeration process by providing nucleation sits for air to accumulate. The vacuum system maintains the heater and deaeration chamber at a low, constant, negative pressure so that the micro bubbles degas and form collection bead sites. When bubbles accumulate, they break away, are pulled through a mechanical ball-valve, and then float into the vacuum system.
    c. Mechanical ball-valve and float: They release accumulated air from the chamber.
    d. Level sensor (LS1): It monitors the water level in the chamber (sensing along analog voltage signals and sends them to a microprocessor after an ADC[1]). The output voltage of LS1 is 4.8 V DC when the chamber is full while it is 3.2 V DC when the chamber is empty ("TRIP POINTS" limits exit for alarms).

7. Post-heater thermistor (T1): It monitors the temperature of the water leaving the heater and deaeration chamber. It is the primary controller of the heater duty cycle but coordinates its operation with T0 (for adjusting the duty cycle of the heater) and T3 (for compensating the natural heat loss as fluid moves through the machine).

8. Deaeration pump (GP1) with check valve: It controls the flow rate in the machine and with GP2 it helps deaerate water coming into the machine. The flow rate is

[1] ADC: Analog to Digital Converter

300 – 600 mL/min except for ACDR where the rinse flow rate is 700 mL/min. The voltage range is 0 – 24 V DC where the gear pump head is magnetically coupled to a 30 V DC motor.

9. Isolation check-valve (ACDR/GP1): It prevents the inlet of GP2 from recording a negative pressure and from reaching the rinse ports when GP1 stops in specific ACDR rinse modes (additional chemicals are drawn in "CLEAN" and "DISINFECTION" modes).

10. Rinse ports (acetate, acid and bicarbonate) and Brown Restrictor: As illustrated by Figure 1, the color code for the concentration lines through which the heated water used for rinsing flows is described as follows: brown for acetate, purple for acid, and orange for bicarbonate solution. The ACDR modes include:

    a. Clean mode: Acetate solution is connected to the yellow chemical port in Figure 1.

    b. Disinfectant mode: Bicarbonate solution is connected to the green chemical port in Figure 1.

    c. Acid rinse mode: The bicarbonate solution line is connected to the chemical container.

    There are two basic procedures involved: the acetate procedure, where the flow runs in the acid and bicarbonate concentrate lines and their corresponding ports which are related to the acetate flow line, and the bicarbonate procedure, where the flow runs in the concentrate lines and the ports which are related to the bicarbonate flow line.

11. Concentrate filters (130 micron): They are used to protect the bicarbonate and acid/acetate diaphragm pumps from being damaged by debris from concentrate containers.

12. Bicarbonate diaphragm pump: It is otherwise recognized as DPB; it has two major functions:

    a. Bicarbonate mode: DPB delivers bicarbonate concentrate into the main flow-path and is mixed with heated water to form the bicarbonate dialysate.

    b. ACDR mode: DPB acts as a disinfection chemical pump when the machine is in "DISINFECT" mode.

13. Bicarbonate mixing chamber: This chamber is used to mix water with bicarbonate concentrate.

14. Bicarbonate control conductivity cell (CC1): This sensor is used by servo-feedback control loop to maintain proportioning of bicarbonate concentrate (ratio 25:1). The system composing of CC1, T3, DPB, and dialysate control microprocessor compares conductivity of CC1 with a selected value from the operator; if the values are different then a correction signal is given to adjust the delivery to DPB. The bicarbonate level of the dialysate solution must be in the range of 20 – 40 mEq/L (mmol/L); this level reading is controlled through the operating parameters 7 and 8.

15. Sample port: It provides a convenience access point for taking bicarbonate samples and for venting excess pressure if the flow-path becomes blocked. Venting helps preventing the tube from becoming disconnected inside the machine. The bicarbonate sample port should be placed in the yellow coded.

16. Bicarbonate monitor conductivity cell (MC1): It maintains bicarbonate conductivity at safe levels (if the level exceeds ± 0.33 mS/cm from set point then the "BICARBONATE CONDUCTIVITY LOW/HIGH" alarm shows).

17. Bicarbonate monitor thermistor (T2): It adjusts the conductivity of MC1 against changes in the dialysate temperature and generates redundant temperature alarms (below 31.7º C or above 43.5º C unless the thermistor T4 indicates same alarm condition). The "HEATER CONTROL DISABLED" alarm appears if T2 reads a temperature higher than 43.5º C.

18. Acid/acetate diaphragm pump (DPA): It has two major functions:

    a. Bicarbonate/acetate mode: The DPA pump delivers acid concentrate into the flow-path during "BICARBONATE" procedure and acetate during "Acetate" procedure. The proportion of acid/acetate to water is 34:1 (range of 34:1 to 44:1 according to the type of acetate used).

    b. Clean mode: The DPA acts as a cleaning solution chemical pump when in "CLEAN" mode. The operator should plug the acetate concentrate line into the yellow chemical port in Figure 1. The port is internally connected to a special container located at the back of the machine. The cleaning agent (usually chloride solution) is drawn up through a 130 micron filter, check valve, and flow switch FSA. FSA monitors pulses from pump to pump to ensure that it does not run out of chemical.

19. Acid/acetate mixing chamber: The mixing acetate concentrate with water during the "ACETATE" procedure, or acid and bicarbonate concentrate with water and during the "BICARBONATE" procedure. It ensures that dialysate is thoroughly mixed before conductivity is measured by final conductivity control cell CC2. Polypropylene pellets are placed in the chamber to enhance mixing and lower overall internal fluid volume to 175 mL. The mechanical float and ball-valve helps removing excess air which accumulates in the chamber. The float acts

against a lever, and it closes the normally opened valve when the fluid level rises while it opens the valve when the fluid level drops. Thus, the float prevents accumulated air from flowing through the final conductivity control cell and routes it to the inlet of vacuum pump (which is directly connected to the drain).

20. Final conductivity control cell (CC2): It is used by the servo-feedback control loop to maintain proportioning of acetate concentrate at a ratio of 34:1 during "ACETATE" procedure, and acid concentrate at nominal ratio between 34:1 and 44:1 during "BICARBONATE" procedure. The system consisting of CC2, T3, DPA, and dialysate prep control microprocessor compares the conductivity measured by CC2 and the value selected by the operator. If the values are different, then the system sends a correction signal to adjust the delivery rate of DPA. The volume of Na^+ can vary from 130 mEq/L to 160 mEq/L.

21. Temperature trim / final conductivity control thermistor (T3): It has 2 primary functions:

    a. Temperature compensation: It adjusts the bicarbonate conductivity of CC1 and CC2 for changes in dialysate temperature. CC1 and CC2 close together in the flow-path and operate with the fluid at the same temperature to provide compensation for both control circuits.

    b. Heater command trim: It maintains the final temperature of fluid going back to the patient by adjusting the command sent to the thermistor T1. The trim function helps compensating for the natural heat loss which occurs as the fluid travels through the machine and for drops in temperature when concentrate solutions are added. The temperature at T1 is normally 1 - 2º C higher or lower than the temperature of the dialyzer.

22. pH probe: It measures the pH via an H ion-exchange method. It monitors the solution flowing just after CC2 and generates an alarm when the pH exceeds specified limits. It protects against the possibility of using wrong concentrate in given mode, i.e. using acid concentrate instead of acetate concentrate in "ACETATE" mode procedure. The pH probe has a high output impedance (100 MΩ) and low DC output voltage (-60 mV / +pH unit) which is proportional to pH of dialysate. Due to the high output impedance, the signal arriving from the pH probe sent directly to dialysate prep CCA through coaxial cable.

23. pH probe fluid ground: It prevents small amounts of electrical (conductivity) current present in dialysate solution from affecting the pH probe. It electrically isolates the dialysate prep and UF[2] modules.

[2] UF: Ultra Filtration

III) Dialysate Prep "ACDR[3]" Section

1. Recirculation Valve (V2): It is a normally closed 24 V DC solenoid valve that opens to recirculate disinfectant solution upstream to inlet of the heat exchanger during ACDR disinfectant mode. Hence, it ensures the hydraulic components at inlet of machine are properly disinfected. GP1 provides the driving force. V2 also opens during ACDR rinse procedures to flush out any chemicals in line and minimize collection of precipitate or other debris.

2. Rinse valve (V7): It is a normally closed 24 V DC solenoid valve that opens only during ACDR rinsing cycle. It provides a pathway from the main flow-path to ACDR flow-path, allowing the machine to automatically rinse the concentrate lines while they are connected to their chemical ports. GP1 pumps the heated water via a rinse port through V7 into the concentrate line connected to chemical ports, and then into ACDR flow-path to drain.

3. ACDR chemical lines and filters (130 micron): They connect lines of back of machine (yellow for cleaning solutions and green for disinfection solutions) to check valve and flow-switch to special chemical port in front (ACDR) panel of machine.

4. ACDR chemical line check-valves: For each chemical line, they are located between the 130 micron filter and T-connection going to flow switch (FSA or FSB) and isolation regulator (PRV4 or PRV5). They prevent a backflow into the chemical containers. The backflow could occur during ACDR rinse and would dilute the chemical making it ineffective. The tubing pressure on the ACDR flow-path side is about 400 mmHg and on 130 micron filter, it is near atmospheric pressure.

5. ACDR pressure regulators (PRV4, 5 & 6): They are adjustable back-pressure regulators (4 and 5) used to stabilize flow switches in chemical rinse flow-path. PRV4 isolates "CLEAN" chemical flow-path and directs the flow to DPB through FSB during ACDR "DISINFECT" mode. Both regulators are calibrated to pressure of about 400 mmHg. PRV6 is an adjustable back-pressure regulator used to keep FS4 flow switch at a positive pressure of around 175 mmHg during ACDR rinse cycles. On the other side of PRV6, the vacuum pressure from GP2 and drain system (vacuum pressure normally-600 mmHg).

6. ACDR chemical line and rinse flow switches (FSA, FSB, FS4, and FSC): FSA and FSB are normally closed flow switches open when flow through them exceeds 34 mL/min. FS4 is a normally closed flow switch that opens at 125 mL/min. FSA, FSB, and FS4 are monitored by both dialysate prep microprocessors. The voltage across the switch contacts is about 0 V DC when the switch is closed (no flow present) and about 4 V DC when it is opened (flow

[3] ACDR: ACiD Rinse

present). FSA monitors yellow chemical port line during ACDR "CLEAN" mode to ensure container doesn't run out of chemical. Each switch pulses open within 0.5 mL stroke of pump. FS4 monitors fluid moving through ACDR flow-path to drain during ACDR rinse cycle. The BiCart switch FSC is used during ACDR rinse modes, when BiCart holder is closed, to ensure that all the bicarbonate solution is rinsed from the system and that the BiCart flow-path is disinfected.

7. ACDR chemical ports (yellow and green): The yellow port is for "CLEAN" port and the green port is for "DISINFECTION" port (mechanically sized so that they can only be connected to correct the concentrate line). The yellow port is connected with the brown acetate line connector, and the green port will mate with the orange bicarbonate line connector. The spring-loaded piston with the O-ring seals the port when the male connector is removed. Each port is internally connected through a flow switch, check-valve, and 130 micron filter to a dedicated chemical container at the back of the machine so that the operator does not come into contact with chemicals when moving concentrate lines during ACDR. The yellow port is typically connected to a container filled with 5.25% $NaHCl_2$ (sodium hypochlorite/bleach). The green port is connected to a container filled with disinfectant such as 37% formaldehyde. In ACDR, the operator may connect either acetate or bicarbonate concentrate line to the designated chemical port. The other port remains connected to the rinse port.

    a. When filling a system with disinfectant chemical, the solution is drawn in by DPB through a 130 micron filter, check-valve, FSB, green chemical port, BiCart module, FSC, another 130 micron filter, pump itself and finally pulsed into the main flow-path just before bicarbonate mixing chamber.

    b. When "DISINFECTANT" rinse mode is in progress, fresh rinse water is provided by GP1 through the acetate rinse port and into V7, through the bicarbonate concentrate line into the green chemical port, through FSB, through PRV5, FS4 and PRV6, and finally to the drain through GP2.

    c. When filling the system with cleaning chemical, the solution is drawn in by DPA through a 130 micron filter, check-valve, FSA, yellow chemical port, pump itself, where it is pulsed into flow-path just before acid/acetate mixing chamber.

    d. When "CLEAN" rinse mode is in progress, fresh rinse water is provided by GP1 through bicarbonate rinse port into V7, through acid and acetate concentrate lines into yellow chemical port, through FSA, PRV4, FS4 and PRV6 and then finally drain through GP2.

IV) Dialysate Prep "Vacuum/Drain" Section

1. Vacuum pump (GP2) and check-valve: GP2 provides a suction force for 2 systems: drain system and vacuum system. It is identical to GP1, but it is driven with a constant voltage of 18.5 ± 0.5 V DC and is usually operated in reverse configuration (reverse polarity and hydraulically connected for reverse flow so it helps GP2 withstand large amounts of air coming from the drain and vacuum lines without decoupling). The drain system begins at the output of PRV1 in ultrafiltration module and proceeds through waste side of heat exchanger. It continues though GP2 (optionally preceded by 158 micron filter), "Waste Handling Option" or WHO and its venturi (pressure vent), and out of the machine through a drain hose. The optional addition of a 158 micron filter (upstream from pump) traps small particles of plastic or other debris that may come through the main flow-path, BiCart module or vacuum system. It helps protect GP2 and prevents loss of vacuum and flow (if present, it must be cleaned every 100 hours of operation. A check-valve placed in parallel with GP2 provides a flow path around the pump head when the pump is not running; it is used during certain passive flow ACDR modes.

2. Vacuum regulator (VR1) and check-valve: The vacuum system composes of GP2, VR1, hydraulic connections to tops of heater/deaeration chamber, bicarbonate and acid/acetate mixing chambers, and air separator. VR1 is a bleed-in, needle type, regulator that allows air into the drain system. The amount of air allowed in controls the suction pressure at the inlet of GP2. The vacuum system is calibrated to a pressure of 450 – 650 mmHg (depending upon the altitude). The check-valve before VR1 prevents the air from flowing back into the chambers when the machine is turned off or when GP2 is shut off during ACDR. Once power which is given to GP2 is off, negative pressure exists in the vacuum line and could draw up unwanted fluid (if it reaches GP1, a false "AIR SEPERATION HIGH" alarm is raised).

3. "Waste Handling Option" (WHO): It is optional and provides convenient inlet to drain system for operator. It handles excess blood, saline, and other liquid waste from blood lines and dialyzer. The operator can dispose of waste by connecting a tube to the WHO inlet port on the front panel and let the gentle suction of venturi system pull the waste liquid to drain. The WHO is designed around the venturi principle. Through the T-connection, the flow is directed both to venturi and up the WHO rinse arm on the front panel of the machine. When the rinse arm is closed, the flow continues through the WHO receiver port, down the suction line, through two check-valves, into the suction port of venturi, and down to drain. When the rinse arm is open, the flow is stopped by internal check-valve and receiver port is opened to atmosphere. The suction line lightly draws air and/or water fluids through the receiver continuously, until it is closed. The check-valves in the receiver/suction line are redundant, ensuring that no flow from GP2 can

come out of WHO assembly through front panel. The WHO should be bleach cleaned routinely as it comes into direct contact with patient fluids and blood.

4. Sample port / pressure vent (clear): The drain relief pressure vent is a clear colored assembly. It is located in the drain line, at outlet of vacuum pump after the WHO flow venturi, and vents at a pressure of about 425 mmHg. It protects against accidental blockages of drain line and is not normally used as a sample port.

V) "Ultra-filtration" Module

1. Balance chamber assembly (including valves and Hall sensors): The ultrafiltration section of the flow-path is designed around a volumetric, closed-loop principle. The first primary component of the section is the balance chamber assembly. The assembly uses 2 synchronized chambers to ensure that the flow to the dialyzer, and the patient, is continuous and that the fluid volume in loop is constant. The balance chamber assembly consists of two identical 125 mL chamber units. When viewed from the rear of the machine, balance chamber 1 becomes on the left while balance chamber 2 becomes on the right. Each chamber includes:

    a. Flexible diaphragm with magnet encapsulated in the center.

    b. Two Hall-effect sensors, one mounted on each side of the chamber at the center. HL1 and HR1 are on chamber 1and HL2 and HR2 are on chamber 2.

    c. Four normally closed 24 V DC solenoid valves, one inlet and one outlet on each side. VB2, 3, 6 and 7 are on chamber 1 and VB0, 1, 4 and 5 are on chamber 2.

    The diaphragm divides the chamber into two halves: one half of the chamber is used to move fresh dialysate while the other half moves waste fluid. With the diaphragm installed, the usable internal volume of the chamber is about 115 mL. The magnet in the center of the diaphragm provides magnetic field that will tell the processor how close the diaphragm is to the wall of the chamber. Viewing the balance chambers from back of the machine, and visualizing the diaphragm magnet, the north pole is to the left and the south is to the right. Hall sensors detect the magnetic field of the diaphragm as it moves inside the chamber. The left Hall sensors HL1 and HL2 have a voltage range of 3 – 6 V DC; the right Hall sensors HR1 and HR2 have a voltage range of 9 – 6 V DC. The output near 6 V means that the magnet is close to the chamber wall. An amplifier conditions this voltage to improve linearity. Its output is then processed by an A/D converter and sent to ultrafiltration control processor. From this voltage processor develops trip points for Hall sensors. Trip points are used for changing valve positions and to keep diaphragms from hitting the chamber walls. The valves control the direction of the fluid through balance chambers. They are electrically connected together in pairs. Each pair, VB0 & 1, VB2 & 3, VB4 & 5, and VB6 & 7, has its own driver

transistor. During normal operation, the valves are opened and closed, four at a time. More specifically, two valves on each chamber are opened while the other two (on both chambers) are closed. Therefore, the fluids enter one side of the chamber while the other side is being emptied. Note that the pairs of valves that open together are on the opposite sides of the chamber which helps flush fresh fluid across the whole surface of the diaphragm. The operation of the balance chambers is built around a "fill" and "cycle" sequence. "Fill" refers to fresh dialysate fluid moving the diaphragm towards the left Hall sensor, and "cycle" refers to waste fluid moving the diaphragm back towards the right Hall sensor. Both movements together complete a full cycle or circuit of balance chamber diaphragm. When calibrated, each chamber moves about 100 to 105 mL of fluid per "fill" and "cycle" sequence. The processor monitors the fill and cycle times for each chamber and uses this information to control the flow pump GP3. The calculations for the fill time of chamber 1 are displayed on the status screen as the flow rate of machine. The chamber is "on-line" when fresh dialysate fluid is being pushed from the chamber towards the patient while it is "off-line" when the right half of the chamber is refilling with fresh dialysate fluid. At the end of the flow in each direction, the processor signals valves to switch and chambers reverse their functions (if VB0, 1, 2 and 3 are open then VB4, 5, 6 and 7 are closed). When commands are sent, all 8 valves reverse their positions, which consequently leads to having one chamber always filling with waste fluid (on-line mode) and pushing fresh dialysate towards the dialyzer while the other is filling with fresh dialysate (off-line mode) and pushing the waste to the drain.

2. Dump valve (V3) and yellow restrictor: V3 is a normally open 24 V DC solenoid valve connected to the balance chambers fresh dialysate inlet line through a yellow restrictor. It provides an alternate path around balance chambers when pressure relief or special flow is required. It opens also for certain alarm conditions. V3 is controlled by the ultrafiltration control processor and is usually open for a short time (< 100 ms) at the end of each cycle (longer periods during ACDR periods). One balance chamber is always filling with fresh fluid while the other is filling with waste. When the right side of the chamber fills first, and the Hall sensor trip points have been reached, V3 is opened to release any excess pressure produced by the flow from GP1. If the other chamber finished filling its left side first, V3 is not used. Rather, the flow pump GP3 will be used to maintain proper pressure in the system. V3 only opens to "dump" excess fresh dialysate to drain if the right chamber fills before the left chamber, in any given cycle. Restated, the dump valve V3 and flow pump GP3 are used to synchronize the chambers, hence preventing the hydraulic lines from separating. The dump valve bypasses fresh dialysate fluid around the balance chambers through PRV1. The yellow restrictor in line with V3 provides resistance to flow so that the pressure through the balance chamber system stays constant when V3 opens and closes.

3. Balance chamber pressure regulators (PRV1 – PRV2): PRV1 and PRV2 are identical, manually adjustable, back-pressure regulators. These regulators perform three major functions:

a. Provide back-pressure through diaphragms so that the inlet pressure to each balance chamber remains essentially constant.
b. Provide stabilizing pressure so that the pressure within the system remains relatively constant and any internal drift is minimized.

c. Isolate the balance chambers from elements downstream (vacuum system or dialyzer) that could affect the flow through the chambers.

PRV1 is calibrated to a specific pressure and is kept there. PRV2 is used to keep the pressure of the waste dialysate basically the same as the pressure of the fresh dialysate. It is calibrated to compensate for differences in system components and minimize drift during normal balance chamber operation.

4. Ultrafiltration pressure regulator (PRV3): It is a manually adjustable, back-pressure regulator. It is set to crack pressure of around 1000 mmHg and isolates the ultrafiltration diaphragm pump DP3 from vacuum state. This high pressure setting is necessary due to positive inlet pressure at DP3 (about 500 mmHg) and negative pressure (> -500 mmHg) of vacuum system. PRV3 prevents fluid from leaking out of the volumetric loop through DP3 to drain.

5. Ultrafiltration diaphragm pump (DP3): It is designed around a volumetric, closed loop principle (flow-path ultrafiltration). It is the second primary component of this section. Its single function is to remove the fluid from the closed loop system. In a volumetric system, there is a constant volume of fluid and a general ambient pressure within the loop. When fluid is removed from the loop, negative pressure is created. The pressure will continue to increase as more fluid is removed or until fluid inlet is provided. In this system, the dialyzer is the normal inlet for the fluid to enter the loop. The fluid drawn from the patient (passing through the dialyzer) is called ultrafiltrate. To protect against pumping the wrong ultrafiltration rate, a metering system turns off whenever the blood pump is off. It also shuts down whenever the flow pump GP3 is turned off or when there is a specific alarm affecting the ultrafiltration system. When the ultrafiltration system off, no fluid moves from the blood side of the dialyzer to the dialysate side.

6. Final conductivity monitor cell (MC2): It assures that the conductivity of the dialysate flowing to the dialyzer is maintained at a safe level. The output displayed on the status screen as the conductivity of the system. It generates a "CONDUCTIVITY LOW" and "CONDUCTIVITY HIGH" alarms if the final conductivity varies by more than ± 0.66 mS/cm from the set point.

7. Final temperature monitor thermistor (T4): It assures that the temperature of the dialysate flowing to the dialyzer is maintained at safe level. Also it is used to compensate the conductivity measuring circuit for changes in the temperature of dialysate. The output of T4 is displayed on the status screen as the system temperature. The "TEMPERATURE LOW" alarm is generated when the

temperature is less than 34º C while the "TEMPERATURE HIGH" alarm is generated when the temperature is higher than 39.5º C; under these conditions, the thermistor T4 protects the patient by putting the machine in bypass mode. If T4 indicates a dialysate temperature higher than 43.5º C, the alarm "DIALYSATE TEMPERATURE LIMIT" is generated and the machine is put into "SHUTDOWN" mode.

8. Bypass valve (V4): It is a 24 V DC 3-way solenoid valve that is used to route dialysate either through the dialyzer lines, or directly to the air separator. Its primary purpose is to prevent unsafe dialysate from flowing into the dialyzer if the alarm condition exists. When the machine is in bypass, there is no flow through the dialyzer lines. The ultrafiltration monitor microprocessor controls the bypass valve. The operator can also manually place the machine into bypass mode by pressing the "BYPASS" switch on communication control panel. The voltage emitted to the valve is about 0 V DC when the machine is in bypass mode and about 24 V DC when connected to the patient circuit. If the power fails, the machine defaults into bypass mode. The switch in the bypass valve monitors the position of the valve; it is normally closed in default position and opens when the bypass valve is energized. If the valve ignores the bypass command or if the switch senses that the valve is in a wrong position, the system activates the "BYPASS VALVE ERROR" alarm and puts the machine into "SHUTDOWN" mode. The ultrafiltration control microprocessor monitors the switch voltage. The voltage across the switch contacts is around 0 V DC when the bypass valve is de-energized (i.e. machine is in bypass) and about 4 V DC when the bypass valve is energized (machine is not bypassed).

9. Dialysate pressure transducers (PDI and PDO): Both transducers monitor the pressure conditions around the dialyzer. The PDI measures the pressure of dialysate solution going into the dialyzer. The PDO measures the dialysate pressure of the solution exiting the dialyzer. Both transducers are identical full-bridge strain gauge type transducers with differential outputs, driven by a 10 V DC excitation voltage and have an output scale factor of 50 μV/mmHg. Both transducers are monitored by ultrafiltration monitor microprocessor (PDO is also monitored by ultrafiltration control microprocessor). PDI is used for "Dialysate Pressure" and TMP[4] calculations. After compensation, the output is displayed on the status screen as dialysate pressure. The dialysate pressure represents the pressure at the center of the dialyzer of formulas:

   Dialysate Pressure = PDI – 38 (Non-bypass mode)
   = PDI – 20 (Bypass mode).

   The PDO is used to help control the speed GP3; it also compensates for changes in the pressure in line between dialyzer and pump. During "AUTOTEST", the PDO controls GP3 entirely but during normal operation, it shares the control with

[4] TMP: Trans Membrane Pressure

balance chambers. PDI and PDO should read within 60 mmHg of each other. If the difference exceeds 400 mmHg, then the alarm "DIALYSATE LINE OCCLUDED" is generated. If the difference is below – 450 mmHg, the alarm "DIALYSATE PRESSURE LOW" is generated while if the difference is above 450 mmHg, the alarm "DIALYSATE PRESSURE HIGH" is generated.

10. Dialyzer fluid grounds: They are located just after PDI and PDO. They prevent small amounts of electrical conductivity current present in the dialysate from reaching the dialyzer or the patient.

11. Sample port / pressure vent (white): It provides a convenient and easy access point for taking dialysate samples, and for venting excess pressure if the flow-path gets blocked. The venting helps prevent the tubing from becoming disconnected inside the machine. Each vent/port assembly is color-coded to avoid confusion (see Figure 1). The dialysate sample port is white and located in the inlet line to the dialyzer. It allows the operator to take the final sample of dialysate with a syringe. The port vents around 850 mmHg of pressure.

12. Dialyzer and connections: The dialyzer is connected to the machine through two dialysate lines. The hose going to the venous end of the dialyzer is called "To Dialyzer" line, and the hose going to the arterial end of the dialyzer is called "From Dialyzer" line. Both hoses are connected to the dialyzer with Hansen type connectors. The blue Hansen connector is mounted into the "To Dialyzer" line while the red Hansen connector is mounted into the "From Dialyzer" line. In the dialyzer, blood and dialysate flow counter-current for maximum exchange of electrolytes and waste products. During basic dialysis, electrolytes are exchanged across the membrane of the dialyzer. During ultrafiltration, the fluid from the blood side of the dialyzer passes through the dialyzer membrane into the dialysate flow-path and into the machine. The fluid transfer is caused by two pressure factors:

    a. Venous pressure of blood.

    b. Changes in fluid volume of the volumetric system.

    The venous pressure is determined by conditions in the patient, blood set, and dialyzer. The fluid and pressure in the volumetric system controlled primarily by GP3, PRV1 & 2, balance chamber assembly, and ultrafiltration pump DP3. To accomplish ultrafiltration, the target for the fluid removal (UF) is programmed in the pressure/UFC screen by the operator. Ultrafiltration can be done without basic dialysis (i.e. the UF is programmed the same way but the machine is in bypass mode). The UF rate determines how fast DP3 will remove the fluid from the closed loop. The fluid leaving the system causes the negative pressure (with respect to the blood side of the dialyzer) to develop, and the dialyzer is the only place where more can be acquired to restore the amount removed. As the ultrafiltrate crosses the membrane, resistance is encountered. The coefficient of

the dialyzer (K_{UF}) will determine how much. Within the specified safety limits, the TMP across the dialyzer will reach whatever level is required to provide the flow demanded by the ultrafiltration metering system. The metering system turns off whenever the blood pump is off.

13. Dialyzer bypass block and sensing switch: The bypass block connects the dialysate lines when there is no dialyzer. It consists of two male Hansen style connector nipples, shunt tube between the two nipples and a micro-switch. The switch assembly detects when the dialysate lines are connected to the bypass block. It is constructed in a way that both the dialysate lines must be connected before it will close. The voltage across the switch contacts is sensed by the ultrafiltration monitor microprocessor, and it is about 0 V DC when the switch is closed while it is about 4 V DC when the switch is opened. The bypass block switch prevents the machine from entering "AUTOTEST" or "ACDR" mode when the dialysate lines are connected to block points. The system generates an "CONNECTORS OFF BYPASS PORTS" alarm if the lines are disconnected during the ACDR procedure. If the hoses are connected to the bypass ports during the recirculate, ready or dialyzer modes, the system will generate "CONNECTORS ON BYPASS PORTS" alarm.

14. Post dialyzer filter: A 158 micron filter can be connected downstream from the dialyzer traps small particles of plastic or other debris that may come out of the dialyzer. It helps protect the gear pumps, valves, and other hydraulic components in the fluid pathway. If the filter begins to clog, the pressure differential between PDI and PDO will increase. If the differential value reaches 400 mmHg, the system generates a "DIALYSATE LINE OCCLUDED" alarm. If the conditions are conductive, the system may also generate "REVERSE TMP" and "LOCALIZED TMP" alarms. The filter should be inspected and cleaned every day.

15. Dialyzer line check-valve: It is located in the "From Dialyzer" line, just after the 158 micron filter. It prevents the fluid from getting out the machine when it is in bypass mode, and the dialyzer lines are temporarily disconnected from bypass block or dialyzer. It also prevents the fluid that has bypassed the dialyzer from flowing into the dialyzer.

16. Air separator: It is a small 130 mL chamber housing:

    a. Mechanical ball-valve and float: They release accumulated air from the chamber. The float acting against the lever which closes the normally open ball-valve when water level rises and opens the ball-valve when the water level drops. This allows the negative pressure which is generated by the vacuum system to pull the air out of the chamber.

    b. Hall effect level sensor (LS2): It monitors the water level in the chamber. LS2 sends the DC voltage signal to the ultrafiltration monitor

microprocessor. The output of the Hall sensor is about 0 V DC when the chamber is full and is about 5 V DC when the chamber is empty. If the water level drops below LS2, the system generates an "AIR SEPERATOR LOW" alarm and shuts off GP3.

c. Conductance probes (CP1 and CP2): They monitor whether the water has passed through the air separator into the vacuum line. CP1 is pulsed by an oscillator and CP2 is connected to the ground. CP1 is normally in contact with air. If water gets through the air separator and touches CP1, a signal from the oscillator is shortened to the ground through the water and CP2. If the processor loses the oscillator signal, then the system generates an "AIR SEPERATOR HIGH" alarm and puts the machine into "SHUTDOWN" mode. The air separator deaerates the fluid coming out of the dialyzer which:

   i. Protects the flow pump GP3 from running dry and wearing out its gears. The air can also cause the pump's magnetic drive to uncouple and stop the flow through the loop.

   ii. Prevents air from flowing into the blood leak detector chamber. The air in the chamber can cause false "BLOOD LEAK" and "BLOOD LEAK WARNING" alarms.

   iii. Prevents the air from entering the balance chambers. The air in the balance chamber compresses and produces erroneous fill and cycle times. This can cause a wrong flow rate to be displayed. Air compression might even cause the chambers to oscillate and display extremely high flow rates (thousands of mL/min).

   The air to and from the air separator hoses can come from several sources:

   i. The system may have had in it when machine was turned on.

   ii. Not all of the air may have been removed from dialyzer (new dry) when it was primed.

   iii. High negative pressure may cause air to come out of the solution in the dialyzer.

   iv. Air may leak into the system through a leaky dialyzer connector or other hydraulic fitting.

   Fluids enter the air separator at the bottom of the chambers, fill the chamber hence pushing the float to the top, and exist through the bottom on the other side. CP1 ensures that the fluid cannot leave the volumetric loop through an illegal means. Loss of fluid could increase the negative

pressure in dialyzer and raise the TMP. The vacuum system ensures that the chamber remains filled, ball-valve is closed, and all air is removed.

17. Flow pump (GP3): The ultrafiltration section of the flow-path is designed around a volumetric, closed loop principle. The third primary component of this section is a flow pump GP3. The function of GP3 is to pull fluid from the dialyzer and push it into the right side(s) of the balance chambers. Restated, the flow pump helps more fluid around the volumetric loop. One balance chamber is always filling with fresh fluid while the other is filling with waste. The chamber filling with fresh fluid is pushing waste fluid to the drain; however, the chamber filling with waste fluid is pushing fresh fluid to the dialyzer. GP3 provides the driving force needed to maintain a continuous flow to the dialyzer. In normal operation, either chamber may finish before the other. When the right side of one chamber fills first, dump valve is opened to release any excess pressure produced by GP1. If the left side of the other chamber finishes filling first, the ultrafiltration control microprocessor slows down, or stops, GP3 to allow the right side time to complete its cycle; V3 is not used. The software stabilizes the delivery rate of flow pump so that the dialysate fluid continuously flows through the dialyzer. The processor uses: “fill” and “cycle” times for balance chambers 1 and 2 along with the pressure signal from PDO to control the speed of GP3. PDO helps regulate the speed of pumps by reporting changes in pressure at the inlet of the pump. If the pressure coming out of the dialyzer decreases, the flow through GP3 also tends to decrease. Using PDO, the processor senses a change in pressure and speeds up GP3 accordingly. If the inlet pressure to PDO decreases, the opposite occurs and the processor slows down GP3 as needed. During the normal flow, the balance chambers perform most of the speed control of GP3; PDO contributes only a small percentage of the control. During the pressure control modes, PDO controls 100% of the speed of GP3. The pressure control is used during “AUTOTEST”, certain alarms and several ACDR mode sequences.

18. Blood leak detector: It is used to monitor the presence of blood in the fluid leaving the dialyzer (indicating rupture in dialyzer membrane). It consists of a cylindrical clear plastic chamber that is covered with opaque heart-shrink tubing, light emitting diode (LED) that transmits modulated infra-red beams, and photo-detection diode sensitive to the infra-red spectrum. The detector automatically calibrated every time the machine is turned on and the temperature is at 34ºC or higher. It also calibrates after a dialysis run (when the machine is put into “SETUP” mode), after ACDR mode has finished and after calibration. Blood entering the chamber absorbs infra-red light and reduces the signal strength of the beam received by the photo-detection diode. If the signal drops low enough, the ultrafiltration monitor microprocessor generates a “BLOOD IN DIALYSATE” alarm and automatically lowers the ultrafiltration rate (programmed by the operator to minimize blood loss). The minimum UFR setting the processor uses to control the flow rate is stored in the operating parameter 15. Blood alerts are detected at two levels: “BLOOD LEAK WARNING” if the detector level decreases more than 53% of the normal value – corresponding to about 0.35

mL/min of 25% of hematocrit blood; “BLOOD LEAK” and “BLOOD LEAK DETECTOR DISABLED” alerts if the detector level decreases more than 61% of the normal value – this corresponds to about 0.45 mL/min of 25% hematocrit blood. If the detector will not calibrate, the system will generate “BLOOD LEAK CALIBRATION ERROR”. Hence, the detector would need cleaning which is performed through a bleach clean sequence or BIAK (Bleach Injector Adaptor Kit).

VI) Additional Hydraulic Component Information

1. Thermistors (T0, T1, T2, T3 and T4): they are part of the simple voltage divider whose DC output voltage changes inversely with temperature. The nominal DC resistance of the thermistor is about 5000 Ω at 25º C and about 3050 Ω at 37º C. The voltage across the thermistor is about 2.5 V DC at 37º C and around 3.1 V DC at 25º C. An amplifier conditions this voltage to improve the linearity. Its output is then processed by an ADC and sent to an appropriate monitor or control processor. The thermistor operations include:

    a. T0 and T1 are part of servo feedback circuit to control the heater’s duty cycle.

    b. T2 is used to compensate MC1 conductivity for changes in dialysate temperature.

    c. T3 is used to compensate CC1 and CC2 conductivity for changes in the dialysate temperature and trim-up temperature command to T1.

    d. T4 is used to compensate MC2 conductivity for changes in dialysate temperature and provides information for the final dialysate temperature reading in the status screen display.

2. Gear pumps (GP1 and GP2): The vacuum pump GP2, rather than the deaeration pump GP1, actually provides most of the deaeration for the system. The primary function of GP1 is to control the flow rate through the machine; on the other hand, both pumps work together. Without the negative pressure generated by GP2, the inlet pressure of GP1 could not go low enough to deaerate the water. The combination of heat (from the heater/deaeration chamber) and maximum low pressure (from the two pumps GP1 and GP2) brings the water close to its vapor point and causes air to come out of the solution. There is a direct hydraulic connection between the inlet deaeration pump GP1 and the vacuum pump GP2 through the heater/deaeration chamber. The chamber is like a giant T-connection with GP1 and GP2 competing for pressure and flow. The maximum inlet pressure pumps can develop is determined by the local altitude and atmospheric pressure (about -600 to -650 mmHg at sea level). The vacuum regulator VR1 is used to control the pressure based on a specific altitude. If either pumps is significantly

weaker than the other, it will not be able to maintain a strong inlet pressure and will be overcome:

a. If GP1 is stronger than GP2, then the vacuum will decrease while the flow rate will increase.

b. If GP2 is stronger than GP1, then the flow rate will decrease while the vacuum will increase.

3. Diaphragm pumps (DPA, DPB and DP3): They are 24 V DC pulsed-operated solenoid type pumps. The maximum delivery rate for these pumps is 100 strokes/min. Through the UF software, DP3 is limited to 80 strokes/min. Each of the pumps has a calibration screw on the back so that it can be calibrated to deliver 0.5 mL fluid pulse or stroke. DPA and DPB can be interchanged with each other; however, they are not interchangeable with DP3. DP3 has a different inlet assembly. A 100º C thermal fuse is built into each pump and provides backup protection to maintain the fuse located on the controller board. The thermal fuse plugs into the back of the solenoid housing in a special socket. High pulse rates (> 100 strokes/min) or failure in solenoid drive circuit 1 can overheat the solenoid and blow the thermal fuse. A 2 A fuse F401 on the dialysate pump CCA provides protection for the solenoids of DPA and DPB. Another 2 A fuse F301 on the ultrafiltration CCA protects the solenoid DP3. These fuses will usually fail before the thermal fuse on the pump.

4. Conductivity cells (CC1, MC1, CC2 and MC2): Each conductivity cell assembly consists of a dual chambered flow tube, circuit card assembly with a transmitter and detector amplifier, and protective cover to protect the cell and circuit card from leaks and fluid spills. The electronic circuit includes two toroidal transformers, a 10 kHz excitation oscillator, and a low-current detection circuitry that senses a current in the fluid path. One transformer is used by an excitation circuit to induce a current into the fluid path, and the second is used to sense electric current in the fluid path – the higher the conductivity of the solution, the higher the current detected. The use of toroid transformers in a dual chambered tube configuration provides isolation between the electronic circuitry and the fluid path – there are no metallic probes actually in contact with the fluid; all signals are inductive. Since there is no actual fluidic contact, this helps preventing magnetic interface between the excitation transformer and detection transformer. It also helps eliminate “cross-talk” between different cells in the system. The operational range of CC1 and MC1 is from 0 mS/cm to 5 mS/cm, and the corresponding output voltage from the conductivity cell circuit card ranges from 0 V Dc to 1.51 V DC at the dialysate temperature of 37º C. The scale factor is 0.302 V DC/mS. The operational range of CC2 and MC2 is from 10 mS/cm to 20 mS/cm, and the corresponding output voltage from the conductivity cell circuit card ranges from 3.02 V DC to 6.04 V DC at the dialysate temperature of 37º C. The scale factor is 0.302 V DC/mS. During calibration, the precision resistors on the dialysate prep circuit card and ultrafiltration circuit card are used to connect

the two transformers together using special dedicated windings. These resistors simulate a known value of conductivity and should cause the cell output a signal within specific reference limits.

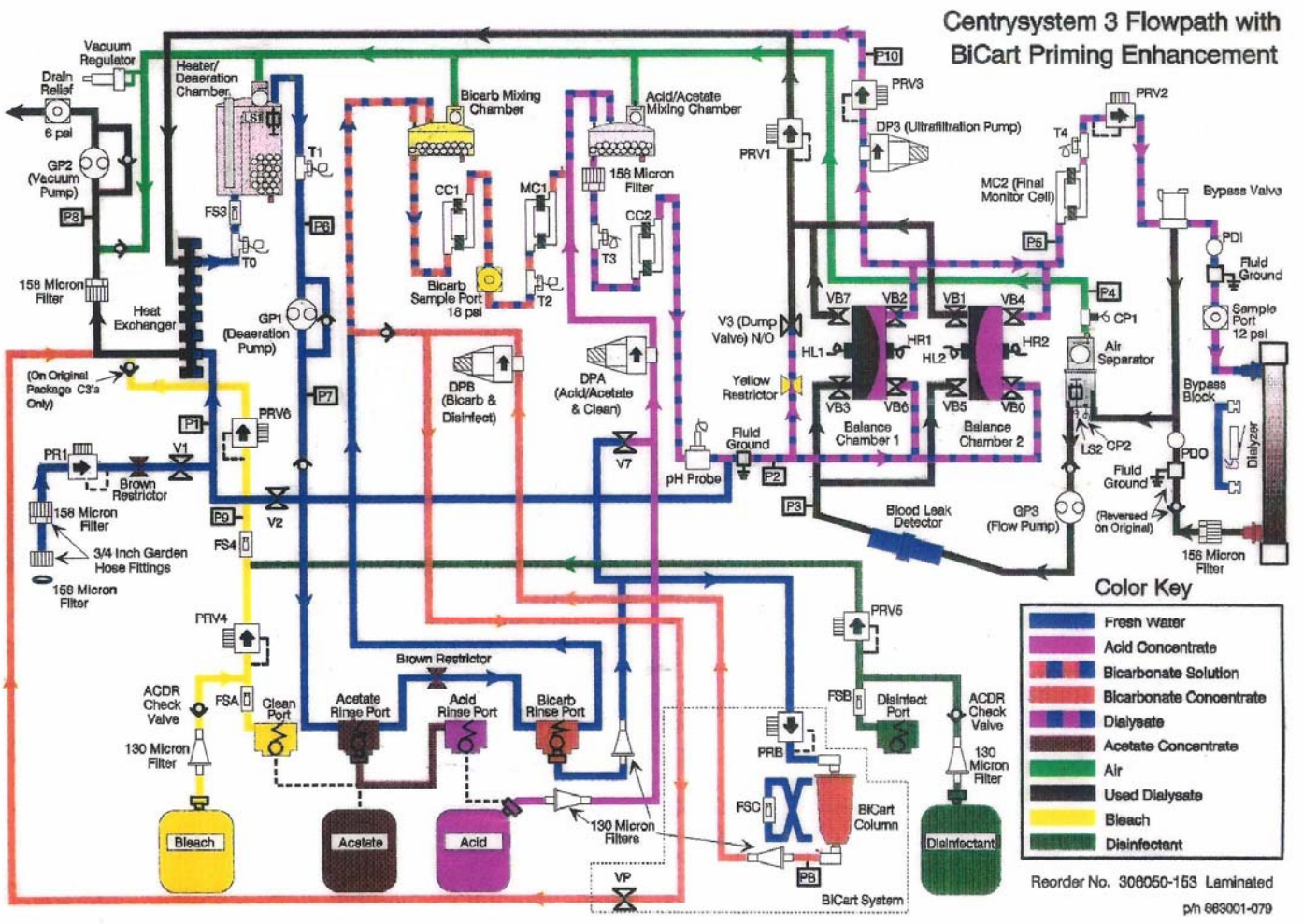


Figure 1 - *Cobe Centrysystem 3 Flow-path Diagram with BiCart Priming Enhancement*

Transmembrane Pressure (TMP):

TMP across any membrane is the difference of the pressure on one side from the pressure on the other. The surface area and the pore size of the membrane will directly affect the flow through the membrane, and the pressure on both sides. The more surface area, the greater the amount of fluid that can pass through the membrane. The larger the pore size, the higher the flow possible through the membrane. Together, these factors produce the capability of the membrane to process fluid. The pore size is often expressed as the coefficient of filtration, and the flow through the membrane is expressed as the filtration rate.

A dialyzer is essentially a very large membrane. It consists of multiple sheets of permeable material, as in a parallel plate dialyzer, or hollow fiber tubes. The dialyzer will process a certain amount of fluid per minute based on the pore size and total surface area of the membrane. In the dialyzer, while one side of the membrane will have blood flow, the other side will have dialysate fluid flow. Note the following definitions as applied to a dialyzer:

TMP	= Transmembrane Pressure	Pressure$_{(w.r.t\ blood)}$ across the dialyzer
UFR/hr	= Ultrafiltration Rate / Hour	Fluid removal from patient / hour
K_{UF}	= Coefficient of Ultrafiltration	Ability of dialyzer to remove fluid (± 20%)

The K_{UF} is a fixed number based on the manufacturing process of the dialyzer. UFR is a number (in kg/hr) generated by the target loss programmed into the pressure / UFC screen by the operator. This entry is converted by the machine to L/hr for TMP calculations.

The transmembrane pressure that will be realized in the dialyzer is:

1. Product of UFR against K_{UF}.
2. Difference between the blood pressure and the dialysate pressure.

The formula of the TMP can be written as:

1. $TMP = UFR / K_{UF} = P_{Blood} - P_{Dialysate}$

   (Centrysystem 3 uses the expression of part 2 for the calculation of TMP ; the venous pressure transducer determines the blood pressure transducer determines the blood pressure and the pre-dialyzer dialysate pressure transducer determines the dialysate pressure). The surface area of the membrane in the dialyzer make it seem like a very long tube; thus, the venous pressure and the pre-dialyzer dialysate pressure will be slightly different than pressures at the center of the dialyzer.

2. A more accurate expression of the TMP calculations involve the center of the dialyzer:

   $TMP_{(Mid\text{-}point)} = P_{Blood\ (Mid\text{-}point)} - P_{Dialysate\ (Mid\text{-}point)}$ (Mid-point = Center)

   To calculate $TMP_{(Mid\text{-}point)}$, the valves for the venous and pre-dialyzer pressures must be compensated (correct static pressure differences as well as dynamic pressure drops). The venous pressure must be raised since it is at the output of the blood side of the dialyzer, which hence provides blood pressure correction. The pre-dialyzer pressure must be lowered since it is at the input of the dialysate side of the dialyzer, which hence provides dialysate pressure correction.

   The pressure formulas become:

   $P_{Blood\ (Mid\text{-}point)} = P_{Venous} + BPC$ (BPC: Blood Pressure Correction factor)
   $P_{Dialysate\ (Mid\text{-}point)} = P_{Dialysate\ (IN)} - DC$ (DC: Dialysate Correction factor)

The dialysate correction factor is fixed by software; it is 20 for the machine when in bypass and 38 otherwise. The blood pressure correction factor is stored in memory in Operating Parameter 11. This parameter should be re-entered as necessary when changing between low K_{UF} and high K_{UF} dialyzers.

The Centrysystem 3 machine calculates the displayed dialysate pressure and TMP:

$$TMP_{(displayed)} = (P_{Venous} + BPC_{OP\ \#11}) - (P_{Dialysate\ (IN)} - 20) \quad \text{(Bypass mode)}$$
$$= (P_{Venous} + BPC_{OP\ \#11}) - (P_{Dialysate\ (IN)} - 38) \quad \text{(Otherwise)}$$

$$P_{Dialysate\ (displayed)} = P_{Dialysate\ (IN)} - 20 \quad \text{(Bypass mode)}$$
$$= P_{Dialysate\ (IN)} - 38 \quad \text{(Otherwise)}$$

Operating Parameter # 10: Maximum TMP allowed (highest value is 700 mmHg) => Limits the displayed TMP on status screen (dialysate section)

Operating Parameter # 12: Maximum allowed difference between $P_{Dialysate\ (Mid\text{-}point)}$ and $P_{Blood\ (Mid\text{-}point)}$

Operating Parameter # 41: Maximum allowed difference between $(P_{Venous} + 0.3*BPC_{OP\ \#11})$ in venous (blue) end of dialyzer and $P_{Blood\ (Mid\text{-}point)}$

Ultrafiltration:

The system of ultrafiltration is designed around a volumetric, closed loop principle. In the volumetric system, there is a constant volume of fluid within a controlled fluid loop. When fluid is removed from the loop, negative pressure is created and consequently the fluid crosses from the blood side of the membrane of the dialyzer to the dialysate side. The fluid passing through the dialyzer (being drawn from the patient) is called ultrafiltration.

To accomplish ultrafiltration, the UF rate is programmed into the pressure / UFC screen by the operator. This rate determines how fast metering system will remove the fluid from the closed loop and suction pressure will develop accordingly. As ultrafiltration crosses the membrane, resistance is encountered. K_{UF} of the dialyzer will determine how much. TMP across the dialyzer will reach whatever level is required to provide the flow demanded by the ultrafiltration metering system.

To protect against pumping the wrong ultrafiltration rate, the metering system turns off whenever the blood pump is off. When the ultrafiltration system is off, no fluid should move across the dialyzer membrane to the dialysate side. Also, if the machine is in bypass mode, there should be no flow through the dialyzer lines. The operator can manually place the machine into bypass mode by pressing the bypass switch on the communications control panel.

Calibration Procedures on Cobe Centrysystem 3:

I) Balance Chamber Calibration:

- Verify that pressure regulators PRV and PRV2 are calibrated as well as pressure transducers PDI and PDO with switches SW2 and SW1-8 are closed (after switching system power off, setting the calibration switches SW2 and SW1-8 to CAL position (i.e. down) is necessary to enter into the calibration mode).
- Switch the power button on, select calibrate option C, and keep selecting until "Balance Chamber" option appears.
- Start calibration.
- Step 1: Bypass the machine by shunting the bypass ports.
- Step 2: Remove bypass mode. The numbers corresponding to LS1 and LS2 appear on the screen (chamber 1 and 2 diaphragms are forced to the left by dialysate prep system in the chamber i.e. HL1 and HL2). The numbers should increase from 0000 to above 0040. If not, then replace the affected CCA Hall-effect sensor. Wait for 2 minutes so the values can stabilize.
- Step 3: GP3 pump forces the chamber diaphragms 1 and 2 to the right side HR1 and HR2.The numbers should start at 00FF and decrease beyond 00D0. If not, then replace the affected CCA Hall-effect sensor.
- Step 4: The numbers of the NOVRAM # 67 to # 70 (UFC 8/6 M&L and UFC 8/7 M&L) appear. Turn the switches on the UF board on and store the values recorded.
- Check the status for dialysate flow (should be ± 30 mL/min within 500 mL/min).
- Check UF service screen 1 (window 1).
- Verify that the control bytes are within 3 of each other: 8M (chamber 1 flow) and 8L (chamber 2 flow).
- Verify that control bytes are within 5 within each other:

  4L (chamber 1 fill time)
  5L (chamber 2 fill time)
  6L (chamber 1 cycle time)
  7L (chamber 2 cycle time)

- Repeat calibration until desired results are reached otherwise set SW2 and SW1-8 open.

II) Dialysate Pressure Transducer Calibration (PDO and PDI):

- There is a need for clamps, a T-connector and a syringe.
- The setup diagram is shown below in Figure 2:

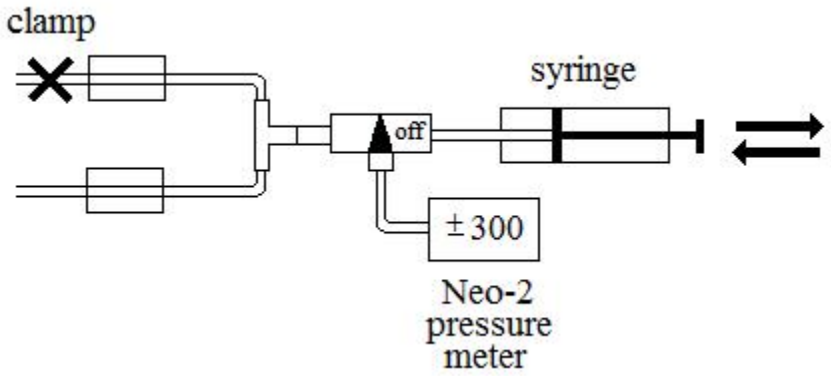


Figure 2 - *Setup for Dialysate Pressure Transducer Calibration*

- Verify switches SW2 and SW1-8 are closed after switching the system power off.
- Switch power button on, select calibrate option C, and keep selecting until "Dialysate Pressure Transducers" option appears.
- Start calibration.
- Step 1: Bypass the machine, clamp the tubing with padded hemostats at output of PDO between PDO and bypass tee. Mark tubing between PDO transducer and check valve with piece of tape. Remove tubing from PDO transducer at check valve. Remove tubing from PDI transducer at fluid ground. Remove any water from tubing. Connect the 2 tubing pieces with chevron or T connector. Connect the pressure meter Neo-2 and syringe to T-connector ports. Adjust the syringe until the pressure meter reads -300 mmHg for 3 seconds. The numbers on the screen should be between 30 to 50 H. Continue the process of calibration.
- Step 2: Adjust the syringe until pressure meter reads 300 mmHg for 3 seconds. The numbers on the screen should be between B0 to D0 H. Continue the process of calibration.
- Step 3: Adjust the syringe until the pressure meter reads -300 mmHg for 3 seconds. The numbers on the screen should read 30 to 50 H. Continue the process of calibration.
- Step 4: Adjust the syringe until the pressure meter reads 300 mmHg for 3 seconds. The numbers on the screen should be between B0 to D0 H. Continue the process of calibration.

- Step 5: The displayed numbers are:

  PDO Gain NOVRAM # 81 – UFC 9/5M (control)
  PDO Offset NOVRAM # 82 – UFC 9/5L (control)
  PDO Gain NOVRAM # 119 – UFM 9/8L (monitor)
  PDO Offset NOVRAM # 120 – UFM 9/9M (monitor)
  PDI Gain NOVRAM # 117 – UFM 9/7L (monitor)
  PDI Offset NOVRAM # 118 – UFM 9/8M (monitor)

- Save and store the parameter values and then switch SW2 and SW1-8 on.

III) Blood Handling Pressure Transducer Calibration (Arterial/Venous Pressure Transducers):

- Set the switches SW2 and SW1-8 down after turning the system power off. Turn the power button on, go to the option "Calibrate", and then select option A "Automatic Calibration". Select "Blood Handling Pressure Transducers".
- Start calibration.
- Step 1: Connect the pressure meter and syringe to the "Venous Pressure" transducer (to the left); adjust the syringe until the pressure reading is 300 mmHg for 3 seconds; continue.
- Step 2: Move the meter and syringe to "Arterial Pressure" transducer; adjust the syringe until the pressure reading is -300 mmHg for 3 seconds; continue.
- Step 3: Move the meter and syringe and open the transducers to the atmospheric pressure for 3 seconds; continue.
- Step 4: The displayed values are:

  Art. Pres. Offset (control) NOVRAM # 129 – BHC 2/6M
  Ven. Pres. Offset (control) NOVRAM # 130 – BHC 2/6L
  Art. Pres. Gain (control) NOVRAM # 131 – BHC 2/7M
  Ven. Pres. Gain (control) NOVRAM # 132 – BHC 2/7L
  Art. Pres. Offset (monitor) NOVRAM # 145 – BHM 2/6M
  Ven. Pres. Offset (monitor) NOVRAM # 146 – BHM 2/6L
  Art. Pres. Gain (monitor) NOVRAM # 147 – BHM 2/7M
  Ven. Pres. Gain (monitor) NOVRAM # 148 – BHM 2/7L

- Save and store the parameter values. Switch SW2 and SW1-8 back on. Prove with the status screen ("Run" mode) that the "Arterial Pressure" and "Venous Pressure" are -4 to 4 mmHg. Connect the pressure meter and syringe to the "Venous Pressure" transducer (left) and adjust the syringe until the pressure is -40 mmHg on the pressure meter while the "Venous Pressure" reads on display -36 to -44 mmHg. Adjust the syringe until the pressure is 380 mmHg; verify the "Venous Pressure" reads 372 to 388 mmHg and clamp the line so that the read pressure is 360 to 400 mmHg with the line clamped. Move the meter and syringe to the "Arterial Pressure" transducer and adjust the syringe similar to the "Venous Pressure" transducer but with

complementary values 40 mmHg, 36 to 44 mmHg, -372 to -388 mmHg, and -360 to -400 mmHg.

- Allow the temperature to stabilize for 5 seconds and monitor the "Venous Pressure" and "Arterial Pressure" for two minutes. If a change of more than 4 mmHg is recorded, locate and repair the leak as well as re-conduct the test.

IV) Dialysate Flow Calibration (GP1):

- Set the switches SW2 and SW1-8 down after turning the system power off. Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "Dialysate Flow".
- Start calibration.
- Step 1: The parameters appearing on the screen are:

Flow Gain	70 – A8 H
Flow Offset	00 – 50 H
Flow / Temperature Corr.	00 – 20 H

The above values are the allowed ranges which can be acquired. If any value is out of its respective range, select "Exit" option B: if the flow gain is out of range, set NOVRAM # 6 to 85 H; if the flow offset is out of range, set NOVRAM # 5 to 35 H; if the flow / temperature corr. is out of range, set NOVRAM # 7 to 06 H. After changing the appropriate NOVRAM parameter, exit and store the value.

- Step 2: A timer of 60 seconds allows the flow to go up to 400 mL/min.
- Step 3: Place the drain hose in a graduated cylinder (of capacity 750 mL) and measure the flow for 1 minute; press modify to change the flow value as indicated by the graduated cylinder (if the value is far off from 400 mL, a higher reading is traced to a malfunctioning flow pump GP2 or GP1 or a leak in the vacuum system while a low reading is traced to a leak in the drain system).
- Step 4: A timer of 60 seconds allows the flow to go up to 600 mL/min.
- Step 5: Place the drain hose in the graduated cylinder and measure the flow for 1 minute; press modify to change the flow value as indicated by the graduated cylinder (if the value is far off from 600 mL, a higher reading is traced to a malfunctioning flow pump GP2 or GP1 or a leak in the vacuum system while a low reading is traced to a leak in the drain system).
- Save and store the parameter values and then switch SW2 and SW1-8 on.
- Select "Run" mode in order to operate the system. The flow should be within ± 30 mL/min form the value of Operating parameter # 21 which corresponds to the dialysate flow rate.

V) Deaeration Level Sensor Calibration (LS1):

- Set the switches SW2 and SW1-8 down after switching the system power off. Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "Deaeration Level Sensor".
- Start calibration.

- Step 1: V1 is turned off so that no water enters the machine; therefore, LS1 is forced to its lowest level. Wait for 1 minute, and then press continue.
- Step 2: V1 is turned full on; hence, LS1 is forced to its highest level. Wait for 1 minute, and then press continue.
- Step 3: The displayed numbers on the screen are:

LS1 Trip Point (hi)	(control)	NOVRAM # 1 – DPC E/5M
LS1 Trip Point (lo)	(control)	NOVRAM # 2 – DPC E/5L
LS1 Trip Point (hi)	(monitor)	NOVRAM # 47 – DPM 3/8M
LS1 Trip Point (lo)	(monitor)	NOVRAM # 48 – DPM 3/8L

- Save and store the parameter values and then switch SW2 and SW1-8 on.
- Select "Run" mode in order to operate the system.
- Verify the readings as follows:
    1. Turn off the water for 1 minute.
    2. Select the DP[5] service screen 6.
    3. The values of the control byte 7M and the monitor byte 7L appear.
    4. Add the bits to each value.
    5. Select the DP service screen E.
    6. Verify that the control byte 5L reads within 5 bits of the monitor byte 7L adjusted value.
    7. Turn the water on, power off then power on.
    8. Press fill and wait 1 minute.
    9. Select the DP service screen 6.
    10. The values of the control byte 7M and monitor byte 7L appear.
    11. Subtract 8 bits from each number.
    12. Select the DP service screen E.
    13. Verify that the control byte 5M reads within 5 bits of the control byte 7M adjusted value.
    14. Select DP service screen 3.
    15. Verify that the monitor byte 8M reads within 5 bits of the monitor byte 7L adjusted value.
    16. If the values fall within specification, the new parameters are reserved; otherwise the calibration process is repeated.

VI) Blood Leak Calibration:

- Set the switches SW2 and SW1-8 down after switching the system power off. Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "Blood Leak Calibration".
- Start calibration (with dialyzer hoses connected to shunt block).
- Step 1: A timer of 20 minutes allows the blood leak detector calibrate.

[5] DP: Dialysate Pressure

- Step 2: The displayed values are as follows:

LED Dark	ADC value with LED off
LED Light	ADC value with LED on
DAC Gain	Blood leak DAC gain
STO AUG	Storage average of light

- Verify that STO AUG is in the range of 5E to 6A H.
- Save and store the parameter values and then switch SW2 and SW1-8 on.

VII) Blood Leak Temperature Compensation Calibration:

- Verify the blood leak temperature compensation by checking the NOVRAM parameter # 122. Select the service screen UFM window B byte 6M, and verify that the value is 67 H. If not, exit the service screen, enter the calibration mode, then select the NOVRAM parameter # 122 and change it to 67 H.
- Set the switches SW2 and SW1-8 down after switching the system power off. Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "Blood Leak Temperature Compensation".
- Start calibration.
- Step 1: A timer allows the machine to stabilize.
- Step 2: Another timer allows the machine to re-stabilize.
- Step 3: The displayed number corresponds to the "Blood Leak Temperature Compensation" gain.
- Save and store the parameter value and then switch SW2 and SW1-8 on.
- Select "Run" mode in order to operate the system.
- Verify that for a temperature range of 30º – 38º C (Operating parameters # 1 and # 2), with dialyzer hoses connected to the dialyzer ("Ready" mode), and with dialysate temperature of 30º C (allow 15 minutes for the system to stabilize), the UF service screen D monitor byte 6M is recorded. When the dialysate temperature is adjusted to 38º C, the UF service screen D gives the monitor byte 6M reading which is within 5 bits from the latter reading (at 30º C).

VIII) Pressure / Flow Correction Calibration:

- PRV1, PRV2, and dialysate pressure transducers PDI and PDO must be calibrated before using this procedure.
- Set the switches SW2 and SW1-8 down after switching the system power off. Place all the concentrate lines in their rinse ports. Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "Pressure / Flow Calibration".
- Start calibration. Verify that the machine is not in bypass mode, and clear the "Dialysate Line Occluded" alarm if necessary.
- Step 1: Wait 2 minutes for the displayed value to stabilize. The pressure value must read about 275 mmHg. Continue.

- Step 2: Wait 1 minute for the displayed value to stabilize. The pressure value must read about -275 mmHg. Continue.
- Step 3: Save and store the parameter values and then switch SW2 and SW1-8 on.
- Select “Run” mode in order to operate the system.
- To verify the values obtained, select the status screen. Adjust the dialysate pressure to -20 mmHg using a syringe placed at the dialysate sample port. After 1 minute, note the chamber 1 fill time (UFC SW1 4L). When the LED DS1 on the UF CCA board is on, inject about 10 cc of water into the dialysate sample port. Verify that the “Dialysate Pressure” is 150 to 300 mmHg (high). The next time DS1 is on (10 to 15 seconds), note the chamber 2 cycle time (UFC SW1 7L). Verify that the difference between the two times of chambers 1 and 2 cycles is less than 0A H. When LED DS1 on UF CCA is on, withdraw 20 cc of water from the dialysate sample port. Verify that the “Dialysate Pressure” is -150 to -300 mmHg (low). The next time DS1 is on (10 to 15 seconds), note chamber 2 cycle time (UFC SW1 7L). Verify that the difference between the two times of chambers 1 and 2 cycles is less than 0A H. Observing the status screen, adjust “Dialysate Pressure” to -8 up to 8 mmHg with syringe placed at the dialysate sample port. The values must be within specification; otherwise, the calibration process is repeated.

IX) UF Pump Calibration (DP3):

- PRV3 must be calibrated before completing this procedure.
- Set the switches SW2 and SW1-8 down after switching the system power off. Fill a beaker (of capacity of 750 mL) with 500 mL of warm water. Clamp the tubing below P10 on the original packaged machines but after P10 on repackaged machines (i.e. not between PRV3 and P10). Uncap P10. Connect one end of the tubing segment to P10, and place the other end in the beaker. Connect the pressure monitoring line to the dialyzer sample port, and place the other end in the beaker. Turn the power button on, go to the option “Calibrate”, and then select option C “Device Calibration”. Select “UF Pump”.
- Start calibration.
- Step 1: Continue.
- Step 2: A timer allows the UF pump to warm up. If the pump is already warm, press the top soft key. When the process is complete, press “Continue”. Place a tubing segment from P10 into a graduated cylinder. Press “Continue”.
- Step 3: Wait for 200 pulses.
- Step 4: Read the amount of fluid present in the graduated cylinder. If the amount is under 80 mL or over 120 mL, manually adjust the UF pump stroke volume screw and retest. Press “Modify” and use the up and down keys to change the screen value to match the measured value.
- Save and store the parameter values and then switch SW2 and SW1-8 on.
- Select “Run” mode in order to operate the system.
- To verify the obtained values, enter into setup mode. Load the fluid filled segment in the air bubble detector. Turn the blood pump on, and press “Pressure / UFC”. Verify that the time left is 4:00 minutes. Adjust the “Target Loss” until “UF Rate” is 2 kg/hr. Empty the graduated cylinder, and replace the tubing from P10 in graduated cylinder.

Press “Mode”, “Ready” and “Dialyze”. Select any UF service screen: when the control byte 3L reads C8 H, move the tubing from the cylinder to a beaker (capacity of 150 mL). Verify that the amount of fluid in the cylinder reads 99 to 101 mL. If the value is within specifications, then remove the tubing and hemostat, recap P10, remove the water filling the tubing and pressure monitoring line, and replace the panels. If not, repeat the calibration process.

X) Blood Pump Flow Calibration:

- Set the switches SW2 and SW1-8 down after switching the system power off. Install a fluid-filled tube into the ultrasonic air bubble detector. Turn the power button on, go to the option “Calibrate”, and then select option C “Device Calibration”. Select “Blood Pump Flow”.
- Start calibration.
- Step 1: Turn the blood pump on. Adjust the flow rate to 100 mL/min. Wait for at least 5 minutes, and then verify that the displayed RPM[6] value is 13.2 to 14.7. If not, increase or decrease the blood pump speed until the displayed RPM meets the specification. Continue.
- Step 2: Adjust the flow rate to 40 mL/min Wait at least 5 minutes, and then verify that the displayed RPM value is 53.4 to 59.0. If not, increase or decrease the blood pump speed until the displayed RPM meets the specification. Continue.
- Step 3: The displayed numbers are:

BP Gain	(high byte)	NOVRAM # 133 – BHC 2/8M
BP Gain	(low byte)	NOVRAM # 134 – BHC 2/8L
BP Offset	(high byte)	NOVRAM # 135 – BHC 2/9M
BP Offset	(low byte)	NOVRAM # 136 – BHC 3/6M

- Save and store the parameter values and then switch SW2 and SW1-8 on.
- Select “Run” mode in order to operate the system.
- To verify the values obtained, press the button “Blood Pump On/Off”, and adjust the blood pump rate to 100 mL/min. Wait 1 minute, and then select the BH service screen 4. Verify that the control word 7 reads 0FBC to 121D H. Adjust the blood pump rate to 400 mL/min. Wait 1 minute, and verify that the control word 7 reads 03FB to 0467 H. If the values do not fall within the given range, repeat the calibration procedure.

XI) pH Probe Calibration:

- Set the bicarbonate level to 20. Place a pair of hemostats (i.e. clamps) on the acid line. Wait 5 minutes. Withdraw dialysate solution from the bicarbonate sample port, and fill one of two 100 mL beakers with the solution. Set the switches SW2 and SW1-8 down after switching the system power off. Fill the second beaker with a 7.0 buffer solution. Fill a 150 mL beaker with RO water. Remove the pH probe from the

[6] RPM: Rotations Per Minute

mounting bracket, and install the mounting cap in place of the probe. Place the pH probe immediately after removing into the beaker filled with RO water (never allow the pH probe to dry out). Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "pH Probe".

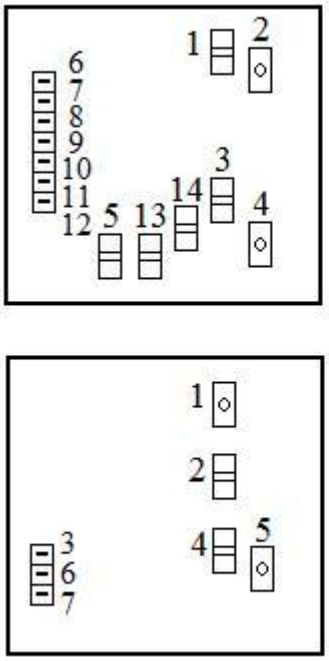
- Start calibration.
- Step 1: Rinse with water, and leave the pH probe in the 7.0 buffer. Wait for 1 minute then press "Continue".
- Step 2: Rinse and leave the pH probe in the bicarbonate solution. Wait for 1 minute then press "Continue".
- Step 3: The displayed values are:

  pH Offset NOVRAM # 46 – DPM 3/7L (02 – 4E H)
  pH Gain NOVRAM # 45 – DPM 3/7M (10 – 6A H)

- Save and store the parameter values and then switch SW2 and SW1-8 on.
- Select "Run" mode in order to operate the system.
- To verify the values obtained, validate that the pH probe is in the bicarbonate solution. Select any DP service screen, and verify that the monitor byte 4M reads A4 to B0 H. Rinse and leave the pH probe in the 7.0 buffer solution. Verify that the monitor byte 4M reads 72 to 7C H. If the values are within specification, turn the power off, replace the pH probe and mount the cap back on the tubing near the probe. Otherwise, recalibrate.

XII) Temperature and Conductivity Calibration:

- Connect all the concentrate lines into their respective rinse ports. Ensure that the NOVRAM parameters # 89 to # 95 are set to their default values: check the UFC SWB bytes 5M, 5L, 6M, 6L, 7M, 7L, and 8M. Turn the power of the system off. Place the conductivity and temperature sensor of the Neo-2 pressure meter in series with the dialyzer hoses (replacing the role of the dialyzer). Place the Hansen connector shunts on the bypass block connectors. Set the switches SW2 and SW1-8 down. Figure 3 illustrates how all the calibration switches should be directed for this procedure.



DP	DP CCA:	SW5	MC1 LO
		SW6	T1
		SW7	T0
		SW8	CC1 LO
		SW11	CC2 LO
		SW12	T3
		SW14	T2
UF	UF CCA:	SW6	MC2 LO
		SW7	T4

Figure 3 - *Diagram Illustrating Position of Calibration Switches on DP and UF CCA Boards*

- Turn the power button on, go to the option "Calibrate", and then select option C "Device Calibration". Select "Temperature and Conductivity".
- Start calibration.
- Step 1: The displayed values correspond to the NOVRAM parameters # 89 through 95. A timer allows the machine to stabilize for 10 minutes (if the timer does not appear, the calibration values of the NOVRAM parameters # 89 through 95 are then out of range; correct them and restart the calibration procedure).
- Step 2: After the timer times out, press "Continue".
- Step 3: The numbers shown are:

T0 Offset	(control)	NOVRAM # 12 – DPC F/6L
T1 Offset	(control)	NOVRAM # 18 – DPC 4/5M
T2 Offset	(monitor)	NOVRAM # 37 – DPM F/6L
T3 Offset	(control)	NOVRAM # 31 – DPC 5/7M
T4 Offset	(monitor)	NOVRAM # 116 – UFM 9/7M
T1 Off Redundant	(monitor)	NOVRAM # 51 – DPM A/6M
T3 Off Redundant	(monitor)	NOVRAM # 36 – DPM 1/6L

  Save the obtained values.
- Step 4: Continue.

- Step 5: Set the following calibration switches upward (indicating normal run mode):

  DP CCA: SW5 MC1 LO
  SW8 CC1 LO
  SW11 CC2 LO

  UF CCA: SW6 MC2 LO

  Set the following calibration switches downward (indicating calibration mode):

  DP CCA: SW9 CC1 HI
  SW10 CC2 HI
  SW13 MC1 HI

  UF CCA: SW3 MC2 HI

  Continue.
- Step 6: The numbers shown are:

CC1 Gain (control)	NOVRAM # 15 – DPC F/8M
CC1 Offset (control)	NOVRAM # 14 – DPC F/7L
CC2 Gain (control)	NOVRAM # 28 – DPC 5/5L
CC2 Offset (control)	NOVRAM # 27 – DPC 5/5M
MC1 Gain (monitor)	NOVRAM # 41 – DPM 3/5M
MC1 Offset (monitor)	NOVRAM # 42 – DPM 3/5L
MC2 Gain (monitor)	NOVRAM # 113 – UFM 9/5L
MC2 Offset (monitor)	NOVRAM # 114 – UFM 9/6M

- Save and store the parameter values and then place all the calibration switches in the normal run position (including the conductivity cells, thermistors, and NOVRAM switches). Switch SW2 and SW1-8 on.
- Select "Run" mode in order to operate the system.

- Concentrate Pump Volume Calibration Verification:

  - Verify that the machine is set for "Bicarbonate" mode. Enter the "Setup" mode and allow the machine to run for 5 minutes without having the concentrate lines connected. While the machine is running, fill a graduated cylinder with 100 cc of water.
  - On the original package machines, clamp the bicarbonate concentrate line on the pump side of the 130 micron filter. On the repackaged machines, clamp the tubing where it enters the diaphragm pump (at rear of panel A).
  - Disconnect the bicarbonate male connector from the rinse port, and remove the tubing from the male connector end of the 130 micron filter. **Immediately** place the tubing with the filter into the graduated cylinder, remove the clamp and start the stopwatch. Allow the machine to pull water from the graduated cylinder for 1 minute after which 45 – 53 mL of water must be left in the graduated cylinder. If the volume is not correct, repeat the process of disconnection, loosen the locking nut on the rear of the bicarbonate concentrate pump, and turn the adjustment screw clockwise to increase the

volume of water left in the graduated cylinder until the volume recording is within range.

- If the concentrate pump was adjusted, secure the adjustment screw by holding the screw and tightening the locking nut (ensure that the adjustment screw does not move). Repeat the step of disconnection until the level left of water in the cylinder is 45 – 53 mL to verify that the calibration did not change after locking the adjustment screw.
- Reassemble the bicarbonate tubing and place the male connector into the bicarbonate rinse port.
- Set SW9 on the dialysate prep. CCA in CAL (i.e. down) position to force the acid pump to run. Fill the graduated cylinder with 100 cc of water.
- Clamp the acid concentrate line at the pump side of the 130 micron filter. Disconnect the acid male connector from the rinse port, and remove the tubing from the male connector end of the 130 micron filter. **Immediately** place the tubing with the filter into the graduated cylinder, remove the clamp and start the stopwatch.
- Allow the machine to pull water from the graduated cylinder for 1 minute after which the level of the water left in the graduated cylinder must be 43 – 53 mL. If the volume is not correct, loosen the locking nut on the rear of the acid concentrate pump and turn the adjustment screw clockwise to increase the volume of water left in the graduated cylinder. Repeat the process until the volume is correct.
- If the concentrate pump was adjusted, secure the adjustment screw by holding the screw and tightening the locking nut; this ensures that the screw does not move. Repeat the process of clamping until the amount of water in the graduated cylinder is specified, thus verifying that the calibration did not change after locking the adjustment screw.
- Reassemble the bicarbonate tubing and place the male connector into the bicarbonate rinse port. Set SW9 on the dialysate prep. CCA in CAL position to force the acid pump to run. Fill the graduated cylinder with100 cc of water. Clamp the acid concentrate line at the pump side of the 130 micron filter. Disconnect the male acid connector from the rinse port, and remove the tubing from the male connector end of the 130 micron filter. **Immediately** place the tubing with the filter into the graduated cylinder. Remove the clamp and start the stopwatch. Allow the machine to pull water from the graduated cylinder for 1 minute after which the level of water left in the cylinder should be 45 – 53 mL. If the volume is not correct, loosen the locking nut on the rear of the acid concentrate pump and turn the adjustment screw clockwise to increase the volume of water left in the graduated cylinder. Repeat the steps of clamping until the level of water in the cylinder is recorded again to verify that the calibration did not change after locking the adjustment screw. Reassemble the acid tubing and place the male connector into the acid rinse port. Set SW9 on the dialysate prep. CCA to normal run position.

- Temperature Calibration Verification:

    - Verify that the command temperature is 37º C. Note the readings of the following parameters (each for 2 minutes, totaling to 10 minutes):

      Measured temperature
      Status screen temperature
      T2 corrected (any DP service screen, monitor byte 3M)
      T3 corrected (DP service screen 5, control byte 7L)
      T3 corrected (DP service screen 9, monitor byte 7L)

    - Calculate average value for each parameter. Verify that the average measured temperature is 36.7º to 37.3º C. Verify that the largest measured deviation from the average is 0.4º C or less.
    - Verify that the average status screen temperature (T4) is within 0.2º C of the average measured temperature. Verify that the average T2 reading (located in any DP service screen, as monitor byte 3M) is A2 to AD H. Also verify that the average T3 reading (located in DP service screen 9, as monitor byte 7L) is 9D to A7 H.

- Acetate/Acid Calibration Verification:

  This verification process is followed alone when there is acid concentrate solution only; when acid is present with bicarbonate solution, the latter calibration verification procedure is followed along with this process.

    - Place the bicarbonate connector in the rinse port. Verify that the machine is in setup mode, and select the acetate procedure. Connect the acetate connector to the acetate concentrate supply or acid connector in the acid concentrate supply.
    - Set the "Sodium Level" to 130 mEq/L. Allow the machine conductivity reading to stabilize (note that one conductivity reading is taken from the reference meter while the other is taken from the screen every 2 minutes, totaling to 6 readings in 10 minutes).
    - Calculate the average measured conductivity and verify that the average measured conductivity is 12.7 to 13.1 mS/cm (CC2 low). Verify that the largest measured deviation from the average is 0.4 mS/cm.
    - Verify that the average screen conductivity is within ± 0.2 mS/cm of the average measured value (MC2 low).
    - Set the "Sodium Level" to 160 mEq/L. Verify that the meter reads 15.4 to 15.8 mS/cm (CC2 high). Also verify that the average screen conductivity is within ± 0.2 mS/cm of the average measured value (MC2 high). Disconnect the acetate/acid supply.

- Bicarbonate Calibration / Stability Verification:

    - Place the acetate and acid connectors in their rinse ports. Verify that the machine is in setup mode with the bicarbonate procedure selected. Connect the bicarbonate connector to the bicarbonate concentrate supply. Clamp the acid line.
    - Set the "Bicarb Level" to 20 mEq/L. Allow the machine conductivity reading to stabilize (note that one conductivity reading is taken from the reference meter while the other is taken from the screen every 2 minutes, totaling to 6 readings in 10 minutes).
    - Calculate the average conductivity, and verify that the average measured conductivity is 1.7 to 2.1 mS/cm. Also verify that the largest measured deviation from the average is 0.2 mS/cm.
    - Verify that MC1 low (bicarbonate corrected conductivity; located in any DP service screen, as monitor byte 3L) reads 57 to 66 H. Set the "Bicarb Level" to 40 mEq/L. Allow the machine conductivity reading to stabilize.
    - Verify that the meter conductivity reads 3.1 to 3.5 mS/cm (CC1 high). Also verify that MC1 high (bicarbonate corrected conductivity; located in any DP service screen, as monitor byte 3L) reads A7 to B6 H.

- Final Conductivity Verification Using Bicarbonate and Acid: (With setting Operating parameter # 5 to 160 H):

    - Place all the concentrate connectors in their rinse ports. Verify that the machine is in setup mode with bicarbonate procedure selected. Connect the acid connector to the acid concentrate supply. Connect the bicarbonate connector to the bicarbonate concentrate supply.
    - Set "Bicarb. Level" to 35 mEq/L and "Sodium Level" to 130 mEq/L. Allow the machine conductivity reading to stabilize (note that one conductivity reading is taken from the reference meter while the other is taken from the screen every 2 minutes, totaling to 6 readings in 10 minutes).
    - Calculate the average measured conductivity, and verify that the average measured conductivity is 12.8 to 13.2 mS/cm (CC2 low). Verify that the largest measured deviation from the average is 0.4 mS/cm or less. Also verify that any screen conductivity is within ± 0.2 mS/cm of any measured value (MC2 low).
    - Set "Sodium Level" to 160 mEq/L. Verify that the meter reads 15.8 to 16.2 mS/cm (CC2 high). Also verify that the average screen conductivity is within ± 0.2 mS/cm of the average measured value (MC2 high). Note that the operating parameter # 5 should be set back to its original value after finishing the verification process.
    - If the above values do not meet the required specification, repeat the calibration procedure. Otherwise, and only if the "Acetate Calibration Verification" does not need to be performed, return the bicarbonate and acid connectors to their rinse ports.